K032608

OCT 2 1 2003

1.6 21 CFR part 807.87(h), **A 510(k)** summary **as described in** Sec. 807.92 **or a 510(k) statement as described in Sec. 807.93.**

SUMMARY:

1.6.1 Sec. 807.92, **Content and format of a 510(k) summary.**

1.6.1.1 (1) The submitter's name, address, telephone number, a contact person, and the date the summary was prepared;

ESTABLISHMENT REGISTRATION-NUMBER:	3003591759	(GONOTEC Gesellschaft fuer Mess- und Regeltechnik mbH, Berlin, Germany)
OWNER-ID:	904 8267	Klaus Noack Taunusstr. 12 14193 Berlin 01149 (0)30 826 36 92
CONTACT PERSON:(Official Correspondent:)		Thomas Bock Celeste Managementberatung Schoenhauser Str.. 73 C 13158 Berlin, Germany Tel: 01149 (0)30 912 085 94 Fax: 01149 (0)30 912 085 91 e-mail: t.bock@celeste-berlin.de

1.6.1.2 (2) The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known;

IN VITRO DIAGNOSTIC PRIMARY CALIBRATOR AS DESCRIBED IN 21 CFR PART 862.1150,

TRADE NAME	CALIBRATION SOLUTION FOR OSMOMAT 010 / 030 / auto
REGULATION NUMBER:	862.1150
PRODUCT CODE:	JIS
COMMON NAME:	CALIBRATOR, PRIMARY; CALIBRATION SOLUTION
ADVISORY COMMITTEE:	CLINICAL CHEMISTRY, (75), CH

1.6.1.3 (3) An identification **of the legally marketed device to which the submitter claims equivalence.**

PREDICATE DEVICE:

510(k)-number	Regulation number	Product Code	decision date	Applicant name	Device name
K931834	862.1150	JIS	08-25-1993	King Diagnostics, registration #: 1827622	Sodium/Potassium standard modified

1.6.1.4 (4) A description of the device that is the subject of the premarket notification submission, such as might be found in the labeling or promotional material for the device, including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties;

A FREEZING-POINT OR CRYOSCOPIC OSMOMETER IS A DEVICE TO MEASURE THE NUMBER OF MOLECULES OR IONS DISSOLVED IN A FLUID, IN THIS CASE, WATER. THE PHYSICAL EFFECT THE MEASUREMENT IS BASED ON IS THAT DISSOLVED SUBSTANCES IN WATER DEPRESS THE FREEZING POINT OF THE SOLUTION. THIS DEPRESSION IN THE FREEZING TEMPERATURE ITSELF, MEASURED EXACTLY, GIVES AN EXACT MEASURE FOR HOW MANY MOLECULES OR IONS ARE DISSOLVED IN THE AQUEOUS CALIBRATOR OR SPECIMEN. THIS EFFECT IS PHYSICAL, WHICH MEANS THAT THE CHEMICAL PROPERTIES OF THE CALIBRATOR OR SPECIMEN REMAIN UNCHANGED. AS ANY DISSOLVABLE SUBSTANCE CAUSES THIS EFFECT, THE RESULT OF THE MEASUREMENT GIVES NO INFORMATION ABOUT THE IDENTITY AND/OR COMPOSITION OF THE SUBSTANCES DISSOLVED, IF THERE SHOULD BE SEVERAL. THE MEASURED VALUE EXPRESSES IF THE RANGE OF OSMOLALITY OF THE SPECIMEN IS TO BE EXPECTED AS BEING NORMAL FOR A SPECIMEN FROM A HEALTHY HUMAN BEING. OR THE OSMOLALITY SHOWS THAT SOMETHING IS WRONG WITH THE PATIENT. FURTHER MEDICAL EXAMINATIONS WOULD FOLLOW. IN THE CALIBRATOR THE ONLY SUBSTANCE DISSOLVED IS SODIUM CHLORIDE. SO THE VALUE OF THE OSMOLALITY ALSO REPRESENTS THE CONCENTRATION OF SODIUM CHLORIDE.

TO MEASURE THE FREEZING-POINT-DEPRESSION, THE SAMPLE IS FROZEN CAREFULLY. THE EXACT TEMPERATURE OF THE FLUID IS MEASURED AT ANY TIME WHILE THE SAMPLE IS COOLED DOWN. THE TEMPERATURE AT WHICH THE FLUID FREEZES TO ICE IS DETERMINED EXACTLY AND THE INTERNAL CALCULATOR OF THE OSMOMETER CALCULATES AND DISPLAYS THE EQUIVALENT OSMOLALITY OF THE LIQUID. IN MATRICES LIKE URINE THE MEASUREMENT SHOWS IF THE KIDNEYS WORK PROPERLY ASSUMABLY.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 2 1 2003

GONOTEC GmbH
c/o Mr. Thomas Bock
CELESTE MANAGEMENTBEARTUNG
SCHOENHAUSER STRASSE 73C
BERLIN
GERMANY 14193

Re: k032608
Trade/Device Name: Calibration Solution for Osmomat 010/030/auto
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIS
Dated: August 19, 2003
Received: August 25, 2003

Dear Mr. Brock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

4.2 Indications for Use

IVD DEVICE CALIBRATION IS MOST COMMONLY PERFORMED USING CALIBRATORS (REFERENCE MATERIALS) SPECIFICALLY INTENDED TO BE USED AS A STANDARD CURVE OR CUT-OFF POINT FOR AN ASSAY.

A CALIBRATOR HAS AN ASSIGNED VALUE THAT IS ESTABLISHED BY THE MANUFACTURER BY A REFERENCE METHOD. CALIBRATORS EXIST IN A VARIETY OF MATRICES SUCH AS SIMULATED AQUEOUS, SERUM, PLASMA OR OTHER TYPES OF SPECIMENS.

PRIMARY REFERENCE CALIBRATORS ARE HIGHLY PURIFIED CHEMICALS THAT CAN BE DIRECTLY WEIGHED OR MEASURED TO PRODUCE A SOLUTION OF KNOWN CONCENTRATION. ALTERNATIVELY, THEY MAY BE MORE COMPLEX BIOLOGICAL MATERIALS HAVING RECEIVED A VALUE ASSIGNMENT USING REFERENCE (STANDARD) METHODOLOGY. THEY ARE SUPPLIED WITH A CERTIFICATE OF ANALYSIS FOR EACH LOT (FOR EXAMPLE, STANDARD REFERENCE MATERIALS (SRMS) FROM THE U.S. NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY (NIST)).

THE PRIMARY CALIBRATOR "CALIBRATION SOLUTION FOR OSMOMAT 010 / 030 / auto" IS USED TO CALIBRATE THE OSMOMETERS "OSMOMAT 030" AND "OSMOMAT AUTO", WHICH BOTH ARE FREEZING-POINT OSMOMETERS FOR USE IN CLINICAL CHEMISTRY. THE OSMOLALITY OF THE CALIBRATOR IS EQUAL TO THE OSMOLALITY OF BODY-FLUIDS (ISOTONIC SOLUTION), PROVIDING THAT THE OSMOMETER WILL BE CALIBRATED CORRECTLY FOR THE FLUIDS TO BE MEASURED FOR MEDICAL PURPOSES.

Jean Cooper

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safe

510(k) K032608